REMARKS

No new claims have been added or amended. Claims 1 through 20 continue to be pending in the application.

Anticipation Under 35 U.S.C §102

Section 102(b) of Title 35 of the United States Code bars the issuance of a patent if "the invention was patented . . . more than one year prior to the date of the application for patent in the United States." "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987).

"It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745 (Fed Cir. 1999); See In re Oelrich, 666 F.2d 578, 581 (CCPA , 1981) (Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.)

Claim Rejections Under 35 U.S.C §102

Claims 1-4 have been rejected under 35 U.S.C. §102 as being anticipated by Psaros. In making the rejection, the Examiner states that Psaros discloses an air-permeable membrane that inherently has sufficient permeability to allow for

patient vocalization. Applicant respectfully requests that the Examiner reconsider this statement since it does not meet the showing required by the courts. Starkly clear is the fact that the Psaros disclosure does not provide a sufficient basis for the Examiner's inherency assertion, since Psaros does not show that the natural result flowing from the operation as taught in Psaros would be to allow for patient vocalization. A review of the Psaros disclosure and knowledge of one of ordinary skill in the art confirms this lack of sufficiency, since:

- Psaros Membrane Has Poor Air Permeability; As pointed out previously, Psaros clearly requires the membrane 46 to be made of a material intended to be permeable to NO and further requires that membrane "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros, column 4, lines 42 and 43.

- The amount of NO (the gas which Psaros requires permeate the Psaros membrane) that is to permeate through the Psaros membrane is exceedingly low. Psaros, column 3 lines 31-40.

- The contemplated amount of NO (the gas which Psaros requires permeate the Psaros membrane) in Psaros is measured in parts per million and is not to be higher than 150-200 ppm. Psaros column 1, lines 54-56. Psaros is additionally clear about the deleterious effect higher concentrations of NO have on the body. Psaros column 1, lines 40-56.

- Vocalization (speaking) requires a substantial air flow, far in excess of the Psaros membrane due to its disparate gas permeability properties. Previously the Examiner's attention was directed to Szachowicz (United States patent No. 4,573,460) cited by the Examiner as "pertinent". Szachowicz indicates that an air flow of "greater than 5 liters/minute" is required for speech. Szachowicz column 1 line 67. Applicant includes with this Response Tanaka, S., W.J. Gould: "Vocal Efficiency and Aerodynamic Aspects in Voice Disorders", Ann. Otol. 94, 29-33 (1985). Tanaka gives a

mean value of 200ml/s (12L/min) as being required for speech. It is well documented in the art[1], also included with this paper, that a mean flow value of, at least, 6L/min is required for speech.

It is clear from a review of the Psaros disclosure that, at least, the claimed elements of an air-permeable membrane having sufficient permeability to allow for patient vocalization are not present. Psaros, as pointed out above, is directed toward a membrane that has limited poor permeability to carbon dioxide, a significant component of expired air. In addition, Psaros is directed toward supplying NO to the lungs during inspiration (See, e.g. abstract, Arrow 18 in Fig. 1 to 3, Arrow 48 in Fig. 5 and 6, Arrow 68 in Figure 7). The present claimed invention is clearly concerned with the expiration of air in order to provide for vocalization. Contrary to the Examiner's assertion on page 7 of the Office Action, the Applicant has positively claimed a quantification of permeability. That quantification clearly is that an airflow required to allow for patient vocalization. Applicant has provided the Examiner with numerous reference materials showing that the airflow, required for vocalization, is well known in the art. It is clear to one of skill in the art that a membrane as taught by Psaros would not meet this airflow requirement. Therefore, a proper rejection under 35 U.S.C. §102 cannot be made.

In addition, the Psaros reference requires a membrane that has poor permeability with regard to carbon dioxide only when the tracheal tube is inserted through the patient's mouth. Psaros does not disclose a tracheal tube (inserted

[1] Hirano, M., Y. Koike, H. von Leden: "Maximum Phonation Time and Air Usage During Phonation", Folia Phoniat. 20, 184 (1968). Isshiki, N., H. von Leden: "Horseness: Aerodynamic Studies", Arch. Otolaryngol, 80, 20 (1964). Isshiki, N., H. Okamura, M. Morimoto: "Maximum Phonation Time and Air Flow Rate During Phonation: Simple Clinical Test For Vocal Function", Ann. Otol 76, 988 (1967). Iwata, S., H. von Leden: "Phonation quotient in Patients With Laryngeal Disease", Folia Phoniat., 22, 117 (1967). Yanagihara, N., Y. Koike, H. von Leden: "Phonation and Respiration, Functional Study in Normal Subjects", Folia Phoniat., 18, 323 (1966). Yanagihara, N., H. von Leden: "Respiration and Phonation: The Functional Examination of Laryngeal Disease, Folia Phoniat., 19, 153 (1967).

through the trachea as in Figure 7), having any membrane, much less an air-permeable membrane. As such, nowhere does Psaros disclose a tracheal cannula...as claimed in, at least, Applicant's claim 1. Applicant additionally points out that carbon dioxide is a well-known and significant constituent of exhaled air[2] The problem to which the Psaros device relates is clearly stated to be a "tracheal tube which makes possible the use of endogenous NO for intubated patients". Psaros, column 2, lines 6-7. The Examiner has pointed to a device, Figure 7, that does not contain a membrane. The lack of a membrane is clearly intended by Psaros, since the only time a membrane is present is when NO is to permeate across the membrane. The Figure 7 device has instead of a membrane an "input port formed by the ejector device 63 and the tube 64 is in this case connected to the Y-piece 8, but could alternatively be connected to the tracheotomy tube 62. The injector device 63 is adapted to draw gas [referring to NO gas] from the upper respiratory tract into the tube 64 and down to the Y-piece 8 by ejector effect when gas flows towards the patient." Psaros, column 5, line 47-53. In the Examiner's asserted configuration, Psaros would not allow for patient vocalization as shown in Figure 7 due to the poor air permeability of the Psaros membrane, AND the configuration would result in respiratory failure of the patient since the non-exhaled carbon dioxide (prevented by Psaros membrane) would invariably cause hypercapnia due to the fact that carbon dioxide could not be exhaled. See P.K. Neema "Respiratory Failure" , Indian J. Anaesth, 47, (5): 360-366, 360. For at least this additional reason, a proper rejection under 35 U.S.C. §102 does not apply.

Furthermore, the Examiner's attempt to bolster the disclosure of Psaros with U.S. Patent No. 6,503,303 to Fuesser is clearly erroneous. **The Examiner has the burden of showing that Psaros discloses, either expressly or inherently, an air-permeable membrane having sufficient permeability to allow for patient vocalization**. As discussed above the Examiner cannot properly meet this

[2] See P.K. Neema "Respiratory Failure", Indian J. Anaesth, 47, (5): 360-366, 360. Copy included with this response.

burden. The Examiner appears to ignore this fact by equating "sound permeable" properties in an **enclosure** for a compressor for a fuel cell drive with a tracheal cannula that allows for patient vocalization. Applicant respectfully reminds the Examiner that the Examiner is required make "a thorough investigation of the available prior art **relating to the subject matter of the claimed invention"** (emphasis added). 37 C.F.R. §1.104(a). Applicant notes that sound permeability and vocalization cannot be equated. The primary larynx sound produces an undifferentiated frequency band, while vocalization is provided by the subsequent free resonancy in the space between the glotis (vocal fold) and the mouth lips and nostrils. See Tanaka, S., W.J. Gould: "Vocal Efficiency and Aerodynamic Aspects in Voice Disorders" page 29; U.S. Patent No. 4,459,984 to Liegner, Column 1, lines 12- 47. See generally, Hirano, M., Y. Koike, H. von Leden: "Maximum Phonation Time and Air Usage During Phonation", Folia Phoniat. 20, 184 (1968). Isshiki, N., H. von Leden: "Horseness: Aerodynamic Studies", Arch. Otolaryngol, 80, 20 (1964). Isshiki, N., H. Okamura, M. Morimoto: "Maximum Phonation Time and Air Flow Rate During Phonation: Simple Clinical Test For Vocal Function", Ann. Otol 76, 988 (1967). Iwata, S., H. von Leden: "Phonation quotient in Patients With Laryngeal Disease", Folia Phoniat., 22, 117 (1967). Yanagihara, N., Y. Koike, H. von Leden: "Phonation and Respiration, Functional Study in Normal Subjects", Folia Phoniat., 18, 323 (1966). Yanagihara, N., H. von Leden: "Respiration and Phonation: The Functional Examination of Laryngeal Disease, Folia Phoniat., 19, 153 (1967). The Examiner should, therefore, reconsider the assertions made in the December 10, 2003 Office Action.

Claims 1-4 are Additionally Non-Obvious Under a Proper 35 U.S.C. §103 Analysis

The claimed invention is additionally non-obvious with regard to, at least, Psaros since there is at the minimum no suggestion or motivation present in the teaching or disclosure of Psaros, or in the references cited by the Examiner, to do what the Applicant has done in the claimed invention. For example, at a minimum a

device having, at least, an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization, is not taught or suggested. In fact, Psaros can be considered, at a minimum, to teach directly against arriving Applicant's claimed invention or produce a non-functional device due to, at least, the Psaros membrane requirements. Applicant notes that as thoroughly discussed by the courts:

> "...the essential factual evidence on the issue of obviousness is set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors)." In re Lee, 61 USPQ2d, 1430 (Fed. Cir. 2002)

Such a rigorous examination required by law clearly would find the claimed invention non-obvious based on at least a study of the problem of allowing patient vocalization while having a tracheal cannula with a cuff in place as solved by the Applicant, and the functionality of the claimed invention. Psaros is directed toward permitting endogenous NO present in the patient's upper respiratory tract, and as such offers no motivation or suggestion to provide an air permeable membrane while allowing a patient to vocalize following a tracheotomy.

Claim Rejections 35 U.S.C. §103

To properly establish a prima facie case of obviousness three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally,

the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §2143.

No Motivation or Suggestion for Proposed Modification and Combination Improper

In order to properly make a prima facie case of obviousness, a motivation or suggestion to combine or modify the references must be shown. The MPEP at §2143.01 states, "[I]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)".

Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. Claims 5-6 depend either directly or indirectly on claim 1, and are patentable for at least the reasons set forth for claim 1. In addition, the rejection of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to modify the teachings of Psaros to arrive at the Applicant's claimed invention, which includes an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. In fact, Psaros would lead one of ordinary skill in the art away from the claimed invention since Psaros requires the membrane 46 to have a "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros, column 4, lines 42 and 43. The amount of NO that is to permeate through the Psaros membrane is disclosed as being exceedingly low. Psaros, column 3 lines 31-40. The contemplated amount of NO in Psaros is measured in parts per million and is not to be higher than 150-200 ppm. Psaros column 1, lines 54-56. Psaros is additionally clear about not having a greater concentration of NO due to its deleterious effect on the body. Psaros column 1, lines 40-56. In addition, Szachowicz (United States patent No.

4,573,460) and the enclosed references directly address some of the requirements for vocalization in a patient. The references clearly identifies that vocalization would not occur by excluding all but a few parts per million of a patient's respiratory gases due to the sheer volume of gases needed for vocalization. Since the proper motivation or suggestion is not present to modify the teaching of Psaros, a rejection under 35 U.S.C. §103(a) is improper.

In addition, the Psaros reference requires a membrane that has poor permeability with regard to carbon dioxide only when the tracheal tube is inserted through the patient's mouth. Psaros does not disclose a tracheal tube (inserted through the trachea as in Figure 7), having any membrane, much less an air-permeable membrane. As such, nowhere does Psaros disclose a tracheal cannula...as claimed in, at least, Applicant's claim 1. Applicant additionally points out that carbon dioxide is a well-known constituent of exhaled air[3] The problem to which the Psaros device is directed is clearly stated to be a "tracheal tube which makes possible the use of endogenous NO for intubated patients". See Psaros, column 2, lines 6-7. The Examiner has pointed to Figure 7 which shows a device not intended to contain a membrane. The lack of a membrane clearly intended by Psaros, since the only time a membrane is present is when NO is to permeate across the membrane. The Figure 7 device has instead of a membrane an "input port formed by the ejector device 63 and the tube 64 is in this case connected to the Y-piece 8, but could alternatively be connected to the tracheotomy tube 62. The injector device 63 is adapted to draw gas [referring to NO gas] from the upper respiratory tract into the tube 64 and down to the Y-piece 8 by ejector effect when gas flows towards the patient." Psaros, column 5, line 47-53. In the Examiner's asserted configuration, Psaros would not allow for patient vocalization as shown in Figure 7 due to the poor air permeability of the Psaros membrane, AND the configuration would result in respiratory failure of the patient since carbon dioxide would invariably cause hypercapnia due to the fact

[3] See P.K. Neema "Respiratory Failure", Indian J. Anaesth, 47, (5): 360-366, 360. Copy included with this response.

that carbon dioxide could not be exhaled. See P.K. Neema "Respiratory Failure", Indian J. Anaesth, 47, (5): 360-366, 360. This clearly would render the Psaros invention being modified unsatisfactory for its intended purpose. As such a proper rejection under 35 U.S.C. §103 is improper.

Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of Muir (U.S. Patent No. 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to provide an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. As discussed above, Psaros requires a membrane that would preclude patient vocalization. Since the proper motivation or suggestion is not present to modify and/or combine the teaching of Psaros with the teaching of Muir, a rejection under 35 U.S.C. §103(a) is improper.

In addition, the asserted combination of the teachings of Psaros in view of the teachings of Muir would create a non-functional device. Muir teaches a valve designed for devices without cuffs. Combining the teaching of such a valve with the teaching of a device with a cuff, as Psaros, would render the patient unable to breath out since the Muir valve closes upon exhalation and the Psaros membrane has, at best, poor permeability to oxygen and carbon dioxide. Carbon dioxide is a well known and substantial constituent of exhaled air. Muir is clear that the valve as taught is closed at all times except during inhalation (emphasis added). Since the membrane as taught in Psaros is, at best, poorly permeable to carbon dioxide, and since the patent cannot exhale via the end of the cannula because of a valve as taught in Muir, the patient will retain carbon dioxide in the lungs. This would clearly imperil the patient. P.K. Neema "Respiratory Failure", Indian J. Anaesth, 47, (5): 360-366. Therefore, the combination of teaching of Muir and Psaros result in a non-functional device since a functional tracheal

cannula that allows for vocalization would not result for the asserted combination of teachings.

Applicant notes that the Examiner's discussion, on page 8 of the December 10, 2003 Office Action, concerning In re Keller and In re Merck & Co. is misplaced. The Applicant clearly is, and has been, asserting that Muir must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole. That teaching is that valve as taught is closed at all times except during inhalation (emphasis added). The Psaros reference teaches a NO permeable membrane which is poorly permeable to carbon dioxide. It is well known that CO_2 removal failure leads to hypercapnia which is considered to be "a medical emergency and a real threat to the life of the patient" P.K. Neema "Respiratory Failure", Indian J. Anaesth, 47, (5): 360-366, 366. The Examiner has cited to no art, and has provided no basis for stating that this combination was within the knowledge generally available to one of ordinary skill in the art. In fact, the Examiner's asserted combination of teachings results in a clearly non-functional device. As such, a proper rejection under 35 U.S.C. §103 does not apply.

Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper

Claims 13-18 and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of Abel (U.S. Patent No. 5,056,515). The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to provide an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. For example, the membrane 46 described in Psaros is, as previously discussed, made of a material intended to be permeable only to NO, and the teachings in Able does not disclose a membrane. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. As discussed above it is clear

that Psaros does not teach or suggest an air permeable membrane that has sufficient permeability to allow for patient vocalization. Since the proper motivation or suggestion is not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 19 Under 35 U.S.C. §103(a) Improper

Claims 19 been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros and Muir as applied to claim 7 above and further in view of Abel (U.S. Patent No. 5,056,515). As discussed above, the combination with regard to, at least, claim 7 is improper. As such, claim 19 is patentable for at least these reasons.

All Claim Limitations Are Not Taught Or Suggested

It is well established that when even one claimed limitation is not found in the combination of prior art, a rejection under 35 U.S.C. §103 is improper. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. The rejection of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted modification would not yield a tracheal cannula with an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. The membrane 46 in Psaros is made of a material intended to be permeable only to NO. Psaros clearly states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Since, at least, the claimed limitation of an air permeable membrane that has sufficient permeability to allow for patient vocalization is not present in the asserted modification, a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros in view of Muir (US 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted combination does not contain an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. Since all the claimed elements are not present a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper

The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization is not present in the asserted combination. Since the all of the claimed elements are not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

The References Teach Away From Each Other

It is a well-established "general rule" that references that teach away cannot serve to create a prima facie case of obviousness. In re Gurley, 27 F3d 551, 553, 31 USPQ 2d 1131, 1132 (Fed Cir. 1994). A "reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant." Winner v. Wang, 202 F.3d 1340 (Fed Cir. 2000) citing Gurley at 553.

The line of development flowing from the Psaros disclosure is unmistakably clear. As discussed above, Psaros is directed toward the use of endogenous NO for intubated patients. This is clear from, at least, Figure 1 where the input port 16 having the membrane 46 is shown in the orotracheal location. This positioning allows for NO present above the membrane to be carried from the upper respiratory tract (nose, paranasal sinus). The Psaros membrane 46, as discussed above, is required not to be an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to

allow for patient vocalization Since it is clear that the line of development flowing from Psaros would not result in the claimed invention, a rejection under 35 U.S.C. §103(a) can not be properly made.

In summary, Applicant has addressed each of the rejections within the present Office Action. It is believed the application now stands in condition for allowance, and prompt favorable action thereon is respectfully solicited.

Respectfully Submitted

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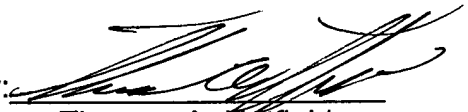
By: 

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